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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/536,735	03/28/00	GAUCH S	OGN-009.2US

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EXAMINER	
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ART UNIT	PAPER NUMBER
1655	8

DATE MAILED: 06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/536,735	GAUCH ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,37-95,112-116 and 121-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,37-95,112-116,124 and 1221* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Europe on 10/23/98 and 4/20/99. It is noted, however, that applicant has not filed a certified copy of the foreign PCT applications as required by 35 U.S.C. 119(b).

Claim Objections

3. Claim 65 objected to because of the following informalities: The clause "phenols ir polyphenols" is found in line 10 of claim 65. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 57, 58, and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification has not been found to teach the conditions under which the various organic dicarboxylic acids recited in claim 51 are to be used; *i.e.*, "oxalic acid, malonic acid, and/or succinic acid." The specification also has not been found to teach the various members of the genus "aldite" and the conditions under which they are to be respectively used (claim 57). The specification has not been found to set forth the reaction conditions under which phenol or polyphenols are used to immobilize nucleic acids. And the specification has not been found to teach the conditions under which each of coating agents identified in claim 72 is to be utilized. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (emphasis added)

For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 51, 57, 58, and 72 are not enabled by the disclosure.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is indefinite with respect to what constitutes an "aldite."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-14, 16-20, 37, 46-48, 66-68, 70, 71, 73-76, 112-116, and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Marquet et al.

9. Marquet et al., column 8, bridging to column 9, the applicability of any of a variety of filtering materials such as membranes, fabrics, fiber mats, films (membranes), etc., that are suitable for isolating DNA and RNA from samples. Crude or processed samples containing the genetic materials are presented to the filtering materials and allowed to pass through, except for the genetic materials which is collected thereon as a result of alcohol precipitation. Through the application of selective dissolving, unwanted fractions, be they chromosomes or RNA are individually removed/isolated from retained plasmid DNA.

10. As seen in column 8, the materials used in the filtering process can be hydrophilic or hydrophobic.

11. Column 9, fifth paragraph, teaches that where membranes are used, the membranes are from 0.1 to 50 microns thick and have a pore size of from 0.1 to 100 microns in diameter.

12. Claims 9-20, 37-42, 46-50, 54-55, 59-65, 76, and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Walter et al.

Walter discloses a device and related method whereby nucleic acid materials is isolated. Column 5 discloses the device as being comprised of a fleece material. In Figure 1 it is apparent that the fleece material, (7) extends across the diameter of the device. The sample which is

applied to the device is first subjected to at least one method step prior to being applied to the device. The preprocessing includes the mixing of the sample with a series of buffers. At least one of the buffers comprises guanidinium HCl and potassium acetate. Once the sample is applied to the device, it is passed through the column or web of fleece as a result of centrifugation. The nucleic acids are precipitated out onto the fleece and are subjected to ethanol precipitation as a buffer of guanidinium HCl and ethanol is passed through the fleece web. The bound nucleic acid is eluted/released by the addition of an aqueous buffer- TE (column 9, fourth paragraph).

13. Claims 9-20, 37-42, 46-49, 54-56, 59-65, 112, 114, 121, and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofstetter et al.

Hofstetter et al., columns 19-20, disclose the isolation of mRNA on a column of oligo-dT cellulose. As seen therein, the cell sample is first subjected to lysis by the use of the chaotropic agent, guanidinium thiocyanate with beta-mercaptoethanol. The sample is applied to the flow-through column whereby the mRNA is non-covalently bound to the oligo-dT molecules located on the surface of the substrate. The RNA is subjected to a salting out as a 5M NaCl buffer is applied to the column. The immobilized RNA is then subjected to wash steps where defined volumes of wash buffer are used (15 ml; column 20, first paragraph). The RNA is then eluted by the application of an aqueous elution buffer. The RNA is then subjected to air drying, followed by dissolving in TE buffer with 0.1% SDS. The resultant mRNA is analyzed by gel electrophoresis and is also used in the synthesis of cDNA (Example 8; column 22).

14. Claims 1, 4, 6-8, 14, 16-20, 37-42, 46-49, 52, 53, 65, 73-75, 112, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Comai et al.

For purposes of examination, the claims have been interpreted as encompassing not only the above disclosed flow-though devices whereby DNA or RNA is/are isolated, but to also encompass traditional hybridization assays and the subsequent stripping of a probe from the hybridization membrane/filter.

Comai et al., column 13, first paragraph, disclose performing a traditional Southern blot whereby a nitrocellulose membrane has a capture sequence immobilized thereon and is subjected to the annealing of a complementary probe. The aspect of immobilizing the probe to the membrane is considered to meet the limitation that the membrane has been coated. Additionally, the use of a prehybridization buffer is also considered to meet this requirement. The hybridization reaction utilizes a high salt buffer (5X SSC; saline sodium citrate). Similarly, the probe is eluted or stripped off of the filter/nylon membrane through the use of a variety of buffers that also comprises SSC.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1, 9, 14, 19, 43-45 and 66-69, 72, 77-95, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marquet et al., in view of Mansfield et al. and Walter et al.

See above for the basis of the rejection as it pertains to the disclosures of Marquet et al., and Walter et al.

Marquet et al., does not disclose performing all of the steps in an automated manner but they do disclose performing certain column operations in an automated manner; see column 18, paragraph six.

The aspect of having the reactions take place in a nearly simultaneous manner is considered to have been met by the prior art as such would be driven by the kinetics of the assay as no special handling or features would be required.

Marquet et al., column 8, disclose that the membrane could be hydrophilic or hydrophobic and that one of skill in the art needs to adapt the degree of hydrophobicity such that the membrane/support/filter would still be functional.

Mansfield et al., column 2, disclose coating hydrophilic membranes such that they would be rendered hydrophobic. Motivation for doing such is found at column 2, penultimate paragraph where it is disclosed that they "would eliminate the need for a blocking agent and therefore would eliminate the need of a membrane wetting step to effect deposition of the blocking agent from aqueous solution."

Column 3, penultimate paragraphs, disclose suitable membranes.

Column 4 discloses the use of the membranes in the isolation of nucleic acids.

Walter discloses a device and related method whereby nucleic acid materials are isolated. Column 5 discloses the device as being comprised of a fleece material. In Figure 1 it is apparent that the fleece material, (7) extends across the diameter of the device. The sample which is applied to the device is first subjected to at least one method step prior to being applied to the device. The preprocessing includes the mixing of the sample with a series of buffers. At least one of the buffers comprises guanidinium HCl and potassium acetate. Once the sample is applied to the device, it is passed through the column or web of fleece as a result of centrifugation. The nucleic acids are precipitated out onto the fleece and are subjected to ethanol precipitation as a buffer of guanidinium HCl and ethanol is passed through the fleece web. The

bound nucleic acid is eluted/released by the addition of an aqueous buffer- TE (column 9, fourth paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the membranes/supports/filters of Marquet et al., and to have further applied the concept of automation as disclosed in Marquet et al., for the obvious advantage of reduced method steps and reproducibility. It would have also been obvious to have modified the methods of Marquet et al., and Mansfield et al., with that of Walter et al., as such allows for a convenient and efficient process whereby nucleic acids are isolated from a sample.

In view of the detailed guidance and explicit teachings of where and how method steps can be reduced or eliminated, the ordinary artisan would have both been motivated and would have had a reasonable expectation of success.

For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 1, 9, 14, 19, 43-45 and 66-69, 72, 77-95, and 123 is considered to be obvious in view of the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephanie Zitomer can be reached on (703) 308-3985. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
June 16, 2001